

REMARKS

Reconsideration and allowance of the present patent application based on the following remarks are respectfully requested.

By this Amendment, claim 1 is amended and claim 16 is newly added. Accordingly, after entry of this Amendment, claims 1-16 will remain pending in the patent application.

Claims 1-8 and 10-15 were rejected under 35 U.S.C. §102(b) based on U.S. Pat. No. 5,215,088 to Normann *et al.* (hereinafter "Normann"). The rejection is respectfully traversed.

Claim 1 recites a nerve or muscle stimulation apparatus comprising, *inter alia*, "a nerve stimulation array electrode comprising a flexible substrate for application to the skin of a user bearing an array of electrodes arranged to be brought into electrical contact with the skin of a user when the substrate is positioned on said skin, ..., and means for securing the array electrode to the skin."

These aspects of claim 1 are amply supported by the original disclosure. As a non-limiting example, one embodiment of the invention discloses an apparatus that includes array electrode 256 having a substrate for application to a skin of a user bearing a plurality of electrodes 257. *See* present application at page 11, lines 12-13 and Figure 5. The substrate is fabricated from a flexible material in order to be mounted on a selected part of the body of the user. *See* present application at page 11, lines 15-16 and Figure 5. The apparatus also includes means for securing the array electrode to the skin, which may consist of, for example, an adhesive or a strap. *See* present application at page 7, lines 26-27, page 8, lines 31-32 and page 9, lines 26-27.

There is nothing in the cited portions of Normann that remotely discloses, teaches or suggests these aspects of claim 1.

The cited portions of Normann disclose a three-dimensional electrode device that includes a plurality of spire-shaped electrodes formed of a semiconductor material. *See* Normann at col. 2, lines 32-51.

That said, the electrode device described in Normann has a rigid base and not a flexible substrate, as recited in claim 1. *See* Normann at col. 2, lines 35-36 and Abstract. Further, the electrode device described in Normann does not comprise means for securing the electrode device to the skin surface as the device of Normann is intended for implantation into the cortex. *See* Normann at col. 2, lines 33-35, col. 4, lines 17-20 and Abstract. Thus, claim 1 is not anticipated by Normann.

Along these lines, by virtue of teaching that the electrode device described in Normann is intended for implantation, there is clearly no motivation or suggestion for one skilled in the art reading Normann to provide the electrode device of Normann with means for securing the electrode device to a skin surface. Therefore, claim 1 is not obvious in view of Normann.

Claims 2-8 and 10-15 are patentable over the cited portions of Normann at least by virtue of their dependency from claim 1 and for the additional features recited therein.

With respect to claim 11, the Office asserts that “the recitation that an element is ‘adapted to’ perform a function is not a positive limitation but only requires the ability to do so perform” and “does not constitute a limitation in any patentable sense.” See Office Action at pages 3 and 4. Respectfully, this is improper.

A functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. *See* MPEP §2173.05(g). Functional language has been held to define present structural attributes of interrelated component parts. *See, In re Venezia*, 530 F.2d 956, 189 USPQ 149 (CCPA 1976). Applicant respectfully submits that is the case here. By way of example, claim 11 recites that the electronic user interface unit is adapted to accept programming to alter the selection of electrodes to accommodate the selection to alterations in the desired site of stimulation with time or user muscle movement. Thus, the electronic user interface unit of claim 11 is not any type of interface unit. Quite to the contrary, the electronic user interface unit of claim 11 has a structural attribute of having the ability to accept programming to alter the selection of electrodes. Nowhere does Normann disclose, teach or suggest such an electronic user interface unit. Without proceeding through each and every claim noted by the Office, Applicant submits that the functional language employed in the claim imparts structural limitations and therefore Applicant respectfully requests that in accordance with MPEP §2173.05(g), each and every recitation be considered in any subsequent Office Action, including those that include the term “adapted to.”

With respect to claim 12, Applicant notes that this claim does not recite the language “adapted to.” Thus, the rejection of claim 12 is improper.

Accordingly, reconsideration and withdrawal of the rejection of claims 1-8 and 10-15 under 35 U.S.C. §102(b) based on Normann are respectfully requested.

Claims 1 and 9 were rejected under 35 U.S.C. §102(b) based on U.S. Pat. No. 5,873,849 to Bernard. The rejection is respectfully traversed.

Claim 1 is recited above. There is nothing in the cited portions of Bernard that remotely discloses, teaches or suggests the above identified aspects of claim 1.

The cited portions of Bernard describe the use of triangular arrays of electrodes to electroporate tissues in vivo. *See* Bernard at col. 3, lines 8-44.

That said, the electrode arrays of Bernard are intended for implantation into a patient. *See* Bernard at col. 3 lines 20-25 and the Examples. As claim 1 recites a means for securing the array electrode to a skin surface, and no such means are disclosed in Bernard, claim 1 is novel over the cited portions of Bernard. Along these lines, by virtue of teaching that the electrode arrays of Bernard is intended for implantation, there is clearly no motivation or suggestion for one skilled in the art reading Bernard to provide the electrode arrays of Normann with means for securing the electrode device to a skin surface. Therefore, claim 1 is not obvious in view of Bernard.

Claim 9 is patentable over the cited portions of Bernard at least by virtue of its dependency from claim 1 and for the additional features recited therein.

Accordingly, reconsideration and withdrawal of the rejection of claims 1 and 9 under 35 U.S.C. §102(b) based on Bernard are respectfully requested.

Claim 16 is newly added to define additional subject matter that is novel and non-obvious. The Office will appreciate that the intention of the present invention is, as set out in paragraph 9 of the application, that muscle stimulation may be achieved without knowing the precise position of the optimum electrode placing, but instead by placing an array electrode on approximately the right area of the skin and, by operation of switches, selecting electrodes until the optimum result is achieved. Muscle stimulation may then be applied to the optimal group of electrodes. These aspects of claim 16 are not disclosed or rendered obvious by the art of record.

Applicant has addressed the Examiner's rejections and respectfully submits that the application is in condition for allowance. A notice to that effect is earnestly solicited.

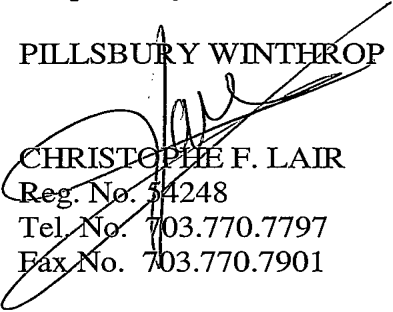
If any point remains in issue which the Examiner feels may be best resolved through a personal or telephone interview, please contact the undersigned at the telephone number listed below.

BIJELIC ET AL. -- 10/587,524
Attorney Docket: 011765-0356407

Please charge any fees associated with the submission of this paper to Deposit Account Number 033975. The Commissioner for Patents is also authorized to credit any over payments to the above-referenced Deposit Account.

Respectfully submitted,

PILLSBURY WINTHROP SHAW PITTMAN LLP



CHRISTOPHE F. LAIR

Reg. No. 54248

Tel. No. 703.770.7797

Fax No. 703.770.7901

JSB/CFL
P.O. Box 10500
McLean, VA 22102
(703) 770-7900